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IN THE UNITED STATES PATENT & TRADEMARK OFFICE

IN RE APPLICATION OF: :

Keiko HASEBE ET AL : EXAMINER: WELLS, L.

SERIAL NO. 09/468,777 :

FILED: DECEMBER 21, 1999 : GROUP ART UNIT: 1619

FOR: AMPHIPATHIC LIPID DISPERSION

DECLARATION UNDER 37 C.F.R. §1.132

ASSISTANT COMMISSIONER FOR PATENTS
WASHINGTON, D.C. 20231

SIR:

Now comes Keiko HASEBE who deposes and states that:

1. I am a graduate of Science University of Tokyo and received my master's degree in the year 1987.

2. I have been employed by Kao Corporation for 14 years as a researcher in the field of cosmetic & toiletries

3. The following experiments were carried out by me or under my direct supervision and control.

Comparative Test

The product of the present invention was compared with comparative products containing no amphipathic lipid with regard to retention or adsorption of the surfactant contained in the products on the skin. The comparative test was carried out according to the following procedure.

Preparation of amphipathic lipid dispersion

The amphipathic lipid dispersion and the solid lipid dispersion as shown in Table 1 below were prepared similarly to the procedure of Example 1 in the present specification. Incidentally, the amounts in the tables are based on % by weight.

Table 1

	Amphipathic, liquid dispersion (Present product)	Solid lipid dispersion (Comparative product)
Amphipathic lipid Formula(1) : $R^1=C_{15}H_{31}$ $R^2=C_{16}H_{33}$ $R^3=H$, $R^4=H$ (melting point 74-76°C)	20.0	
Solid lipid: Ethyleneglycol distearate (melting point 60-65°C)		20.0
Decyl polyglycoside (condensation degree 1-1.35)	12.5	
Polyoxyethylene lauryl ether sulfate sodium salt (EO=3)		4.2
Palm kernel fatty acid diethanol amide		12.0
Water	Balance	Balance
Total	100.0	100.0
Appearance	Pearl	Pearl
Average particle size (μm)	11.8	8.1

Amount of surfactant retained on the skin

After the forearm part each of five healthy male subjects was preliminarily cleaned, a glass cup was attached thereto. Each of systemic cleansing agents A, B and C shown in Table 2 was diluted to three times with an ion exchange water and poured into the glass cup. Each subject was subjected to a cup-shake treatment for ten minutes. After treatment, the treated forearm part was rinsed sufficiently with ion exchange water,

lightly removed of water with a paper towel, and allowed to dry for 30 minutes. Then the stratum corneum of the forearm part was collected by means of a tape stripping method. Lauryl ether acetate, which is a main surfactant of the systemic cleansing agents, was extracted from the tape used for the collection, and subjected to a high speed liquid chromatography to determine the amount of the lauryl ether acetate[1] adsorbed and retained on the skin.

The systemic cleansing agent A is a blank and contains neither an amphipathic lipid dispersion according to the invention nor a solid lipid dispersion that is not within the present invention. Systemic cleansing agent B corresponds to a product of the present invention. Systemic cleansing agent C has a pearl-like luster and contains a solid lipid having a particle size similar to that of the amphipathic lipid contained in the present product but does not contain any amphipathic lipid according to the present invention.

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[1] the amount of the lauryl ether acetate is indicated by the total amount of polyoxyethylene(4,5) lauryl ether acetate sodium salt and polyoxyethylene(10) lauryl ether acetate sodium salt.

Table 2

	Systemic cleansing agent A	Systemic cleansing agent B	Systemic cleansing agent C
	Blank (comparative product)	Present product	Comparative product
Polyoxyethylene (4,5) lauryl ether acetate sodium salt	7.0	7.0	7.0
Polyoxyethylene (10) lauryl ether acetate sodium salt	7.0	7.0	7.0
Decyl polyglycoside (condensation degree: 1-1.35)	2.5	2.5	2.5
Lauric acid amidopropyl betaine	5.0	5.0	5.0
Coconut oil fatty acid monoethanol amide	2.7	2.7	2.7
RHEODOL TW-IS339C *1	3.0	3.0	3.0
Amphipathic lipid dispersion *2		5.0	
Solid lipid dispersion *3			10.0
Water	Balance	Balance	Balance
Total	100.0	100.0	100.0

*1: Kao, polyoxyethylene sorbitan fatty acid ester

*2: the amphipathic lipid dispersion shown in Table 1

*3: the solid lipid dispersion shown in Table 1

The results are shown in Table 3.

Table 3

	Amount of lauryl ether acetate salt in stratum corneum ($\mu g/cm^2$-skin)		
	Systemic cleansing agent		
	A (Blank)	B (Present product)	C (Comparative product)
Average adsorption amount ±SD	3.0 ± 0.9	1.3 ± 0.5	3.2 ± 0.5

From the results in Table 3, it will be apparent that the present product significantly reduces adsorption of the surfactant on the skin whereas comparative product C without any amphipathic lipid does not exhibit such effect although it contains a solid lipid having a particle size similar to that of the amphipathic lipid contained in the present product.

4. The test method used to determine surfactant skin adsorption is an art recognized test and provides statistically significant results.

5. The difference between a surfactant adsorption of $1.3 \pm 0.5 \mu m/cm^2$ -skin and a surfactant adsorption of $3.0 \pm 0.9 \mu m/cm^2$ -skin is commercially significant as the consumer can detect the difference.

6. I declare under penalty of perjury that the foregoing is believed to be true and correct.

Keiko Hasebe

Signature

NOV. 16. 2001

Date